

**Testimony**  
**Of**  
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**U.S. House of Representatives**  
**Committee on Commerce**  
**Subcommittee on Telecommunications, Trade, and Consumer Protection**  
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I have the unique opportunity to testify before you today, not just as the President and Founder of the Center for Patient Advocacy, a grassroots organization dedicated to ensuring that all Americans receive the best quality health care available, but also as a practicing orthopedic surgeon who has been involved in the research and development of new medical devices for over fifteen years. I know firsthand how innovative technology leading to the development of new medical devices can not only save, but also improve the lives of countless patients. Thus, I am here today not just on behalf of the scientists, physicians and researchers who dedicate their lives to developing new medical devices, but more importantly, on behalf of the millions of Americans who, today and in the future, depend on the medical advances in the field of biotechnology that have occurred in large part because of ready access to biomaterials.

Look how far we have come in such a short period of time. Many people in the Washington D.C. area recently saw a Washington Post article that told the courageous story of one of the Center's members who was burned over 65% of his body. Given a 50-50 chance to survive, this young man's life was saved by an innovative medical device, a type of artificial skin called Integra. The biomaterial silicone contained in the Integra prevented life-threatening fluid loss and infection and helped facilitate the healing process. Thanks to the availability of biomaterials,

this young man is not only alive to tell his remarkable story, but he is now able to resume his career as an orthopedic surgeon.

This is not an isolated example illustrating the critical role biomaterials play in the development of state-of-the-art patient care. Today, young children born with heart defects no longer are sentenced to a life of inactivity or death. These defects now can be repaired with artificial implants, made with a variety of biomaterials, that allow these children to lead normal, active lives. Infants and children with hydrocephalus, a condition in which fluid surrounding the brain accumulates endlessly, resulting in mental retardation and often death, may now grow up to be productive members of society because a simple shunt made of silastic can be implanted to drain the excess fluid.

It is not just our children who benefit from the life-saving and life-enhancing medical devices that are so dependent on the supply of biomaterials. Our parents and grandparents benefit from the hundreds of thousands of artificial hip and knee joints implanted each year. Only with the availability of advanced biomaterials has the development of total joint replacement been possible. Now our senior citizens stricken with arthritis can remain ambulatory without pain for the rest of their lives, whereas not too many years ago, an arthritic hip or knee meant years of debilitating pain and dependency on others.

Today, you have heard the story of a young woman who has beaten the odds of bone cancer without a disfiguring amputation -- which was the standard of care just a few years ago. Without the biomaterial polyethylene, this would not have been possible.

Implantable pacemakers, defibrillators and heart valves have prolonged the lives of millions of Americans who in years past would have surely succumbed to the ravages of heart disease. Without biomaterials, these critical life-saving cardiac devices would simply not be available.

But, is this so-called "biomaterials crisis" a real threat to quality patient care in this country? The answer to this question is simple and straightforward. Yes, the biomaterials crisis is real, and yes, its effects are being felt today. Since 1994, at least 12 suppliers of biomaterials have chosen to stop selling their products to medical device manufacturers. They are leaving the market not because they are finding more profitable markets outside the biotechnology world, but simply because of the enormous costs of litigation. Even though, in most cases, biomaterials suppliers have no direct involvement with the design, manufacture or sale of the medical device, the mere threat of litigation has scared them away from the medical device market. In fact, a 1995 study conducted by the Department of Health and Human Services concluded that the current situation "will have an immediate and significant adverse impact on health care and may eventually shift basic biomaterial research overseas."

Can we afford to stand by as the number of biomaterials suppliers continues to dwindle? Must we wait to take action until one day there will be no medical devices on the shelf to save and improve the lives of our children and parents? Or, should we act wisely and responsibly now to protect the future health of all Americans?

Responsible legislation is clearly needed to address the biomaterials crisis and ensure that the patients of today, as well as those of future generations, have access to the highest level of health care in the world. Legislation must prevent the exodus of biomaterials suppliers from the medical device market while at the same time preserving a patient's fundamental right to proceed against a supplier when it is actually involved in the design, manufacture or sale of an allegedly defective medical device. It is imperative that any legislative efforts not only protect the legal rights of patients, but also protect the rights of patients to continue to have access to all the wondrous life-saving and life-enhancing medical devices that modern science has afforded us.

If legislation is not enacted and fails to protect the precious supply of the biomaterials needed to continue the manufacture of medical devices, who will take responsibility for the lives lost and suffering left untreated? In the interest of quality patient care and the millions of Americans who depend on the supply of biomaterials to allow them access to the medical devices they desperately need, the Center for Patient Advocacy urges you to support legislation that will ensure that ready access to biomaterials never ends.

Thank you.